

\* NOTICES \*

## Machine Translation of Reference 4

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CLAIMS

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## [Claim(s)]

[Claim 1] In a medical-application guidewire provided with a core wire formed so that a tip part might become thin, and a coil which a tip part periphery of this core wire was equipped with, adhered a end face in the middle of said core wire, and adhered a tip to a tip of said core wire, and a head round together, A medical-application guidewire, wherein said coil comprises a wire rod of metal gradually made thin towards a tip.

[Claim 2] The medical-application guidewire according to claim 1 which comprises a wire in which, as for said coil, the sectional shape makes a round shape.

[Claim 3] The medical-application guidewire according to claim 1 which comprises a line of an irregular shape cross where, as for said coil, the sectional shape makes shape except circular.

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[Translation done.]

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## DETAILED DESCRIPTION

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### [Detailed Description of the Invention]

#### [0001]

[Industrial Application]This invention relates to the guidewire of the medical application used when inserting a catheter in a blood vessel, a ureter, a bile duct, a trachea, etc., for example.

#### [0002]

[Description of the Prior Art]Inserting a catheter, prescribing drugs, such as a contrast medium, for the patient, or extracting some organizations with forceps etc. through a catheter is performed for the inspection and the therapy in the tubular organ of human bodies, such as recent years, for example, a blood vessel, a ureter, a bile duct, and a trachea. He is trying to extract a guidewire, after inserting a first comparatively thin and flexible guidewire and inserting a catheter in accordance with the periphery of this guidewire into a tubular organ on the occasion of insertion of a catheter.

[0003]As the above-mentioned guidewire, the tip part of core wires, such as (1) stainless steel and a shape memory alloy, is formed in tapered shape, for example, What covered synthetic resin membrane on the periphery, and (2) A safety wire and an inner core wire are inserted in the inside of the coil of what adhered the coil which carried out the adhesion volume of the thin wire rod to the tip part of the comparatively thick core wire, and (3) adhesion volumes, and various kinds of things, such as what adhered to the coil, are proposed in those ends.

[0004]The guidewire 31 indicated as an example by JP,3-122849,U by these people is shown in drawing 4. That is, one end of the metal coil 37 of the diameter of the same was mostly soldered by the tip part 35 in which this guidewire 31 makes the tapered shape of the metal wire 32, and the other end of the metal coil 37 has adhered to the curved surface shape head 36 by soldering. And further, the metallic mesh 33 has been arranged in said metal coil 37, the one end adhered to the tip part 35 of said wire 32, and the other end 34 has adhered to said head 36.

[0005]The guidewire 41 similarly indicated as other examples to the application-for-utility-model-registration common No. 65422 [ four to ] by these people is shown in drawing 5. That is, as for this guidewire 41, the core wire 42 is constituted from that of two or more metal thin wires by the line, and the tip part of the core wire 42 is making the diameter reduction part 43 through the taper part 45. The coil 47 of a shape memory alloy is arranged at the periphery of the taper part 45 of the core wire 42, and the diameter reduction part 43, and this coil 47 adheres that tip to the head 46 together with the tip 44 of said core wire 42, and adheres that end face to the taper part 45 of the core wire 42 by the metal wax material 48.

#### [0006]

[Problem(s) to be Solved by the Invention]In order to make such a guidewire insert in the course which the blood vessel etc. bent, sufficient pliability is needed for the tip part so that an organization may not be wounded, and a certain amount of rigidity is needed for the base side so that operation with a hand may be transmitted. It is necessary to lead to a direction of movement correctly, and he makes a determined direction rotate a guidewire by a hand part in this case towards the direction of a request of the tip part of a guidewire, and is trying to turn the tip part of a guidewire towards desired in the part where the blood vessel etc. branched, or the curved part. For this reason, the rotation transmission nature which tells the torque in a hand even to a tip part is also required of a guidewire.

[0007]However, since drawing 4 and the guidewire shown in 5 were not enough as the pliability of the coil with which the tip part of the core wire was equipped, there was a possibility that the accident in which a tubular organ is accidentally broken through at the time of insertion might occur. In order to increase the pliability of a coil, it is possible to make the wire size of a coil thin, or to open a coil pitch and to make the initial tension low, but there is an intensity maximum community also in making the wire size of a coil thin, and a coil gap may be caused if a coil pitch is opened too much.

[0008]Therefore, without spoiling the operativity from the hand side, there is the purpose of this invention in providing the medical-application guidewire it enabled it to insert safely, even when the pliability of a tip end part is fully acquired and inserts in the large portion of winding of a tubular organ.

#### [0009]

[Means for Solving the Problem]In order to attain the above-mentioned purpose, a medical-application guidewire by this invention, In a medical-application guidewire provided with a core wire formed so that a tip part might become thin, and a coil which a tip part periphery of this core wire was equipped with, adhered a end face in the middle of said core wire, and adhered a tip to a tip of said core wire, and a head round together, Said coil comprises a wire rod of metal gradually made thin towards a tip.

[0010]According to one of the desirable modes of this invention, said coil comprises a wire in which the sectional shape makes a round shape.

[0011]According to another desirable mode of this invention, said coil comprises a line of an irregular shape cross where the sectional shape makes shape except circular.

[0012]  
[Function]As for the guidewire of the medical application by this invention, the tip part of the core wire is formed thinly.  
And the coil with which the tip part periphery of the core wire was equipped can also abolish a possibility of injuring or breaking through an organization, when the pliability excellent in the tip part is acquired and inserts into the bent tubular organ, since it comprises a wire rod of the metal gradually made thin towards the tip.

[0013]Since it constituted from a wire rod of the metal which turned at the tip the coil with which the tip part periphery of the core wire was equipped, and was gradually made thin, the base side of a coil has comparatively high rigidity, and it is not spoiled so much, the operativity, for example, the rotation transmission nature etc., from the hand side, etc.

[0014]The sectional shape of a coil may be a wire, and may be a line of an irregular shape cross, and can acquire the outstanding pliability by considering it as the shape to which all are becoming thin gradually toward the tip part. Width can be given to the pliability of a coil part by combining with the tapered shape of a core wire.

[0015]  
[Example]The sectional view in which drawing 1 shows one working example of the medical-application guidewire of this invention, and drawing 2 are the sectional views showing the shape before processing of the coil used for the guidewire.

[0016]This medical-application guidewire 11 comprises the metaled core wire 12, the coil 17 of the metal which adhered to that tip part periphery, and the round head 16 provided at those tips.

[0017]As the core wire 12, elastic metallic materials, such as stainless steel, a shape memory alloy, and piano wire, are used preferably, for example. The core wire 12 may comprise a cabling reliance line not only in what consists of one wire but in two or more small-gage wires. The tip part 13 of the core wire 12 is formed so that tapered shape and the shape of a stage may be made, for example and it may become thin gradually. The range of the diameter of the core wire 12 is about 0.1-3 mm, moderate elasticity and rigidity are obtained according to the purpose, and it is determined that it is moreover easy to insert. 30-500 mm is suitable for the length of the tip part 13 by which the diameter of the core wire 12 was reduced. The tip of the core wire 12 has adhered to the head 16.

[0018]Although gold, platinum, tungsten, etc. which have roentgenopaque property are preferred as the coil 17, especially tungsten is preferred in respect of the polishing work mentioned later. May use elastic metallic materials, such as the core wire 12, same stainless steel, a shape memory alloy, piano wire, and in that case, After performing polishing work mentioned later, it is preferred to form the tunic of radiopacity substances, such as gold, platinum, and tungsten, in the surface by methods, such as plating, ion plating, sputtering, vacuum evaporation, and CVD.

[0019]By processing the coil 17a (refer to drawing 2) formed with the wire rod of the same wire size by chemical polishing, electrolytic polishing, or other means, the coil 17 is formed so that a wire size may become thin towards a tip.

[0020]When the wire rod is fabricated by stainless lines, chemical polishing can be performed by pulling up a coil little by little, for example as the tip part of a coil is immersed into this and it passes through time using etching reagents, such as ferric chloride solution.

[0021]When a wire rod is a stainless material, mixed liquor, such as phosphoric acid, sulfuric acid, and chromic acid, is used for electrolytic polishing, and it is performed 30 thru/or by electrolyzing for 10 minutes as current density 30 thru/or 100 A/dm<sup>2</sup>, for example. It can carry out by pulling up a coil little by little as the tip part of a coil is immersed into an electrolysis solution also in this case and it passes through time.

[0022]The latest wire size of the coil 17 compares with the original wire size preferably. It is ideal to use 1/2 or less. When the coil 17 consists of construction material which does not have the roentgenopaque property of stainless steel etc., it is preferred to form the tunic which consists of a roentgenopaque substance, as mentioned above.

[0023]On the periphery of the coil 17, in order to raise the slide nature to a catheter, synthetic resin coatings, such as a fluoro-resin, may be covered. Hydrophilic polymer may be covered on the surface of the synthetic resin membrane. As such hydrophilic polymer, resin which was indicated by JP,4-14991,B, for example is mentioned.

[0024]In this way, as for the formed coil 17, the end with a thicker wire size adheres to the root 15 of the tip end part 13 of the core wire 12 by a metal wax, plasma arc welding, etc., respectively on the head 16 in which the end with a wire size thinner again makes the shape of a hemisphere together with the tip 14 of said core wire 12. As for the width dimension of metal soldering, it is preferred to be referred to as at least 1 mm or more. Said head 16 makes the duty which prevents the damage to the tubular organ wall in the time of the insertion on the occasion of insertion to the tubular organ of the guidewire 11.

[0025]Processing of chemical polishing of the coil 17, electrolytic polishing, etc. can also be performed together with the core wire 12, after adhering to the core wire 12 as mentioned above.

[0026]Drawing 3 is a sectional view showing other working example of the medical-application guidewire of this invention.

[0027]The core wire 22 in which the diameter of the tip part 23 was reduced like said working example as for the guidewire 21 of this working example, It is arranged at head [ which adhered to the tip 24 of this core wire 22 ] 26,

and tip part of core wire 22 23 periphery, a end face is adhered to the base side of said core wire 22, and the tip consists of the coils 27 which adhered to said head 26.

[0028]And this working example differs in that the wire in which sectional shape makes a rectangle is used as said coil 27. In this case, the point processed so that it may become thin as the wire size of the coil 27 goes to a tip part is the same as said working example.

[0029]As shown in drawing 6 (a), a section may be a square wire which makes square shapes, such as a square, or the coil used for the guidewire of the medical application of this invention may be a crushing line which makes the shape where the section crushed the circle as shown in the figure (b). Thus, a section can also use the line of various irregular shape crosses which makes the shape except circular.

[0030]Since the wire size of the coil portion was thinly formed to the direction of a tip one by one, pliability of the guidewires 11 and 21 of the medical application of this invention by each above-mentioned working example improved much more, and they were able to be inserted safely, without injuring an organization also to the large tubular organ of winding by this.

[0031]

[Effect of the Invention]As explained above, in this invention, the wire size of the coil was thinly formed in the direction of a tip one by one.

Therefore, pliability improves much more, and it becomes easy by this to insert in the organic portion of a tubular organ in which winding is large especially, and damage to the organ in the time of insertion can be prevented.

Since the wire size of the coil is thin as it becomes in the direction of a tip, a coil's own outer diameter also becomes small and insertion to a tubular organ becomes easy. As compared with the case where the wire size of the whole coil is made small, the convectivity of operation by the side of a hand is also good, and it excels also in intensity.

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## DESCRIPTION OF DRAWINGS

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**[Brief Description of the Drawings]**

[Drawing 1]It is an important section sectional view showing one working example of the medical-application guidewire by this invention.

[Drawing 2]It is a sectional view showing the shape before processing of the coil used for the guidewire.

[Drawing 3]It is an important section sectional view showing other working example of the medical-application guidewire by this invention.

[Drawing 4]It is an important section sectional view showing an example of the conventional guidewire.

[Drawing 5]It is an important section sectional view showing other examples of the conventional guidewire.

[Drawing 6]It is a sectional view showing other examples of the coil used for the medical-application guidewire by this invention.

**[Description of Notations]**

11 and 21 Guidewire

12 and 22 Core wire

13 and 23 Tip part

16 and 26 Head

17 and 27 Coil

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[Translation done.]

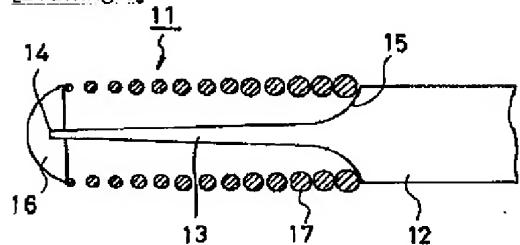
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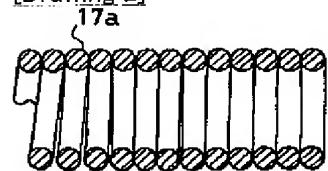
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## DRAWINGS

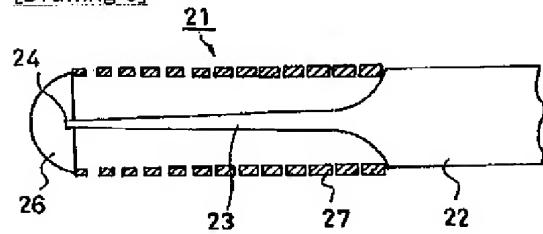
## [Drawing 1]



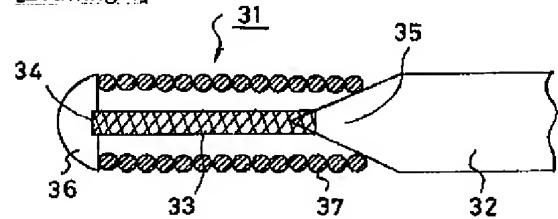
## [Drawing 2]



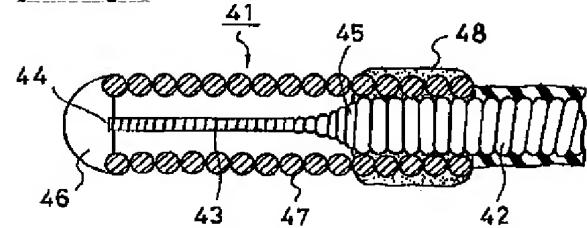
## [Drawing 3]



## [Drawing 4]



## [Drawing 5]



## [Drawing 6]



(a)

(b)

[Translation done.]

## PATENT ABSTRACTS OF JAPAN

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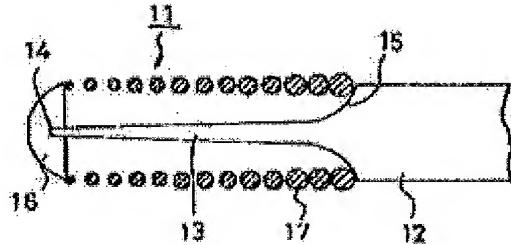
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**(54) GUIDE WIRE FOR MEDICAL TREATMENT**

**(57)Abstract:**

PURPOSE: To provide a guide wire which has excellent resilience at its front end part and is safely insertable into the vascular organs without damaging their tissues.

CONSTITUTION: This guide wire 11 is constituted by finely forming the front end 13 of a core wire 12, mounting a coil 17 at the outer periphery of the front end 13, fixing the base end of the coil 17 to the middle of the core wire 12 and fixing the front end of the coil 17 together with the front end 14 of the core wire 12 to a round head part 16. A wire which is finely formed to the diameter gradually decreased toward the front end is used as the coil 17. The coil 17 may consist of the round wire or the wire having a modified cross section exclusive of the round wire.



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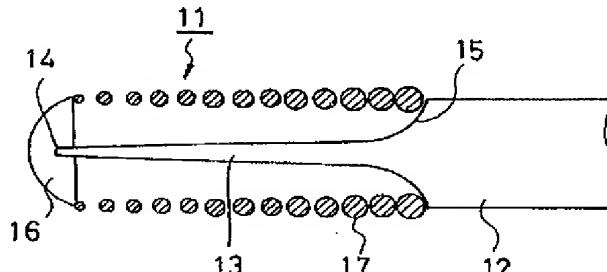
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(54)【発明の名称】 医療用ガイドワイヤ

(57)【要約】

【目的】 先端部分の柔軟性に優れ、管状器官の組織を損傷することなく、安全に挿入できるようにした医療用ガイドワイヤを提供する。

【構成】 芯線12の先端部13を細く形成し、この先端部13の外周にコイル17を装着し、コイル17の基端を芯線12の途中に固着し、コイル17の先端を芯線12の先端14と一緒に丸い頭部16に固着してなるガイドワイヤ11において、コイル17として、その線径が先端部に向かって徐々に細く形成されたものを用いる。コイル17は、丸線からなるものでも、丸線以外の異形断面の線からなるものでもよい。



## 【特許請求の範囲】

【請求項1】先端部が細くなるように形成された芯線と、この芯線の先端部外周に装着され、基端を前記芯線の途中に固着され、先端を前記芯線の先端と一緒に丸い頭部に固着されたコイルとを備えた医療用ガイドワイヤにおいて、前記コイルは、先端に向けて徐々に細くされた金属の線材で構成されていることを特徴とする医療用ガイドワイヤ。

【請求項2】前記コイルは、その断面形状が円形をなす丸線で構成されている請求項1記載の医療用ガイドワイヤ。

【請求項3】前記コイルは、その断面形状が円形以外の形状をなす異形断面の線で構成されている請求項1記載の医療用ガイドワイヤ。

## 【発明の詳細な説明】

## 【0001】

【産業上の利用分野】本発明は、例えば血管、尿管、胆管、気管などにカテーテルを挿入する際に用いられる医療用のガイドワイヤに関する。

## 【0002】

【従来の技術】近年、例えば血管、尿管、胆管、気管などの人体の管状器官における検査・治療のため、カテーテルを挿入して造影剤等の薬剤を投与したり、カテーテルを通して鉗子等によって組織の一部を採取したりすることが行なわれている。カテーテルの挿入に際しては、管状器官内に、まず、比較的細くて柔軟なガイドワイヤを挿入し、このガイドワイヤの外周に沿ってカテーテルを挿入した後、ガイドワイヤを抜き出すようにしている。

【0003】上記ガイドワイヤとしては、例えば、(1)ステンレス、形状記憶合金等の芯線の先端部をテープ状に形成し、外周に合成樹脂膜を被覆したもの、(2)比較的太い芯線の先端部に、細い線材を密着巻きしたコイルを固着したもの、(3)密着巻きのコイルの内部に、安全ワイヤと内芯ワイヤとを挿入して、それらの端部をコイルに固着したものなど、各種のものが提案されている。

【0004】図4には、一例として、本出願人による実開平3-122849号に開示されたガイドワイヤ31が示されている。即ち、このガイドワイヤ31は、金属ワイヤ32のテープ状をなす先端部35に、ほぼ同一径の金属コイル37の一端がろう付けされ、金属コイル37の他端は曲面状の頭部36にろう付けにより固着されている。そして更に、前記金属コイル37内には、金属メッシュ33が配置され、その一端は前記ワイヤ32の先端部35に固着され、他端34は前記頭部36に固着されている。

【0005】図5には、他の一例として、同じく本出願人による実願平4-65422号に記載されたガイドワイヤ41が示されている。即ち、このガイドワイヤ41は、芯線42が複数本の金属細線のより線で構成され、

芯線42の先端部はテープ部45を経て縮径部43をなしている。芯線42のテープ部45及び縮径部43の外周には形状記憶合金のコイル47が配置され、このコイル47はその先端を前記芯線42の先端44と一緒に頭部46に固着され、その基端を芯線42のテープ部45に金属ろう材48によって固着されたものである。

## 【0006】

【発明が解決しようとする課題】このようなガイドワイヤは、血管等の曲折した経路に挿入させるため、先端部には組織を傷付けないように十分な柔軟性が必要とされしており、基部側には手元での操作が伝達されるようある程度の剛性が必要とされている。又、血管等の分岐した箇所や曲がった箇所において、ガイドワイヤの先端部を所望の方向に向けて、進行方向に正しく導く必要があり、この場合、ガイドワイヤを手元部分で所定方向に回転させ、ガイドワイヤの先端部を所望の方向に向けるようしている。このため、ガイドワイヤには、手元での回転力を先端部にまで伝える回転伝達性も要求される。

【0007】ところが、図4、5に示すガイドワイヤでは、芯線の先端部に装着されたコイルの柔軟性が十分でないため、挿入時に誤って管状器官を突き破るという事故が発生する虞れがあった。コイルの柔軟性を増すためには、コイルの線径を細くしたり、コイルピッチを開いて初張力を低くすることが考えられるが、コイルの線径を細くするのにも強度上限界があり、コイルピッチを開きすぎるとコイルずれを起こす可能性がある。

【0008】したがって、本発明の目的は、手元側からの操作性を損なうことなく、先端部分の柔軟性が十分に得られ、管状器官の曲折の大きい部分に挿入する場合でも安全に挿入できるようにした医療用ガイドワイヤを提供することにある。

## 【0009】

【課題を解決するための手段】上記目的を達成するため、本発明による医療用ガイドワイヤは、先端部が細くなるように形成された芯線と、この芯線の先端部外周に装着され、基端を前記芯線の途中に固着され、先端を前記芯線の先端と一緒に丸い頭部に固着されたコイルとを備えた医療用ガイドワイヤにおいて、前記コイルは、先端に向けて徐々に細くされた金属の線材で構成されていることを特徴とする。

【0010】本発明の好ましい態様の1つによれば、前記コイルは、その断面形状が円形をなす丸線で構成されている。

【0011】本発明の別の好ましい態様によれば、前記コイルは、その断面形状が円形以外の形状をなす異形断面の線で構成されている。

## 【0012】

【作用】本発明による医療用のガイドワイヤは、芯線の先端部が細く形成されており、しかも芯線の先端部外周に装着されたコイルも、先端に向けて徐々に細くされた

金属の線材で構成されているので、先端部に優れた柔軟性が得られ、曲折した管状器官内に挿入するときに、組織を損傷したり突き破ったりする虞れをなくすことができる。

【0013】また、芯線の先端部外周に装着されたコイルを、先端に向けて徐々に細くされた金属の線材で構成したので、コイルの基部側は比較的剛性が高く、手元側からの操作性、例えば回転伝達性などもそれほど損なわれない。

【0014】なお、コイルの断面形状は、丸線であってもよく、また異形断面の線であってもよく、いずれも先端部に向って次第に細くなっている形状とすることにより、優れた柔軟性を得ることができる。また、芯線のテープ形状と組み合わせることにより、コイル部の柔軟性に幅を持たせることができる。

【0015】

【実施例】図1は、本発明の医療用ガイドワイヤの一実施例を示す断面図、図2は、同ガイドワイヤに用いられるコイルの加工前の形状を示す断面図である。

【0016】この医療用ガイドワイヤ11は、金属の芯線12と、その先端部外周に固着された金属のコイル17と、それらの先端に設けられた丸い頭部16とで構成されている。

【0017】芯線12としては、例えばステンレス、形状記憶合金、ピアノ線などの弾性金属材料が好ましく使用される。また、芯線12は、1本のワイヤからなるものばかりでなく、複数の細線をより合わせたより線で構成されていてもよい。芯線12の先端部13は、例えばテープ状や段状をなして、次第に細くなるように形成されている。芯線12の直徑は、0.1～3mm程度の範囲で、目的に応じて適度な弾性、剛性が得られ、しかも挿入しやすいように定められる。また、芯線12の縮径された先端部13の長さは、30～500mmが適当である。芯線12の先端は、頭部16に固着されている。

【0018】コイル17としては、X線不透過性を有する金、白金、タングステンなどが好ましいが、後述する研磨加工の点でタングステンが特に好ましい。また、芯線12と同様なステンレス、形状記憶合金、ピアノ線などの弾性金属材料を用いてもよく、その場合には、後述する研磨加工を行った後、その表面に金、白金、タングステンなどのX線不透過物質の被膜を、めっき、イオンプレーティング、スパッタリング、蒸着、CVDなどの方法で形成することが好ましい。

【0019】コイル17は、同じ線径の線材で形成されたコイル17a(図2参照)を、化学研磨、電解研磨等の手段で加工することにより、先端に向けて線径が細くなるように形成される。

【0020】化学研磨は、例えば、線材がステンレス線により成形されている場合、塩化第2鉄水溶液などのエッチング液を用い、この中にコイルの先端部を浸漬して

時間を経るに従って少しづつコイルを引き上げることにより行うことができる。

【0021】また、電解研磨は、例えば、線材がステンレス材の場合、焼酸、硫酸、クロム酸などの混合液を使用し、電流密度30乃至100A/dm<sup>2</sup>として、30乃至10分間電解することによって行われる。この場合も、電解液中にコイルの先端部を浸漬して時間を経るに従って少しづつコイルを引き上げることにより行うことができる。

【0022】なお、コイル17の最先端の線径は、好ましくは、元の線径と比較して1/2以下にすることが理想的である。また、コイル17がステンレス等のX線不透過性を有しない材質からなる場合は、前述したように、X線不透過性物質からなる被膜を形成することが好ましい。

【0023】また、コイル17の外周には、カテーテルに対する滑り性を向上させるため、フッ素樹脂等の合成樹脂被膜を被覆してもよい。更に、その合成樹脂膜の表面に親水性ポリマーを被覆してもよい。このような親水性ポリマーとしては、例えば特公平4-14991号に開示されたような樹脂が挙げられる。

【0024】こうして形成されたコイル17は、金属ろう、プラズマ溶接などにより、線径の太い方の端は、芯線12の先端部分13の付け根15に、また線径の細い方の端は、前記芯線12の最先端14と一緒に半球状をなす頭部16にそれぞれ固着される。なお、金属ろう付けの幅寸法は少なくとも1mm以上とすることが好ましい。前記頭部16は、ガイドワイヤ11の管状器官への挿入に際して、その挿入時での管状器官内壁への損傷を防止する役目をなすものである。

【0025】なお、コイル17の化学研磨、電解研磨等の加工は、芯線12に上記のように固着した後に、芯線12と一緒に行うこともできる。

【0026】図3は、本発明の医療用ガイドワイヤの他の実施例を示す断面図である。

【0027】この実施例のガイドワイヤ21は、前記実施例と同様に、先端部23が縮径された芯線22と、この芯線22の最先端24に固着された頭部26と、芯線22の先端部23外周に配置され、基端を前記芯線22の基部側に固着され、先端を前記頭部26に固着されたコイル27とで構成されている。

【0028】そして、この実施例は、前記コイル27として、断面形状が長方形をなす平線が用いられている点が異なっている。この場合、コイル27の線径が先端部に向かうに従って細くなるように加工されている点は、前記実施例と同様である。

【0029】なお、本発明の医療用のガイドワイヤに用いるコイルは、図6(a)に示すように断面が正方形などの角形をなす角線であってもよく、あるいは同図(b)に示すように断面が円を潰した形状をなす潰し線

